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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/929,924      | 08/15/2001  | David M. Center      | 12861A              | 1129             |

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EXAMINER

ANDRES, JANET L

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/929,924             | CENTER ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Janet L. Andres        | 1646                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 April 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 21 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 29-31,33 and 34 is/are allowed.
- 6) Claim(s) 21 and 32 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \*    c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 23 April 2004 is acknowledged. Claims 21 and 29-34 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### ***Election/Restrictions***

2. Applicant notes that claim 34 was withdrawn from consideration. Claim 34 was rejoined in paragraph one of the office action of 21 October 2003.

### ***Claim Rejections/Objections Withdrawn***

3. The objection to the specification as lacking identifiers for all sequences is withdrawn in response to Applicant's amendment.

4. Applicant's amendment with respect to color drawings is noted. However, color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied. The specification has been amended, but neither a petition nor colored drawings have been filed.

5. The rejection of claims 21 and 29 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn in response to Applicant's arguments.

***Claim Rejections Maintained***

6. The rejection of claims 21 and 32 under 35 U.S.C. 103(a) as unpatentable over the '933 patent in view of Harlow et al. is maintained for reasons of record in the office action of 21 October 2003.

Applicant argues that neither reference provides a teaching or suggestion to make antibodies against the 16mer of claim 32. Applicant further argues that the existence of methods for generating antibodies does not motivate the artisan to generate antibodies against the peptides of the invention. Applicant additionally argues that hindsight reasoning has been used in searching for fragments of the claimed peptide and that this is not permissible under the law.

Applicant's arguments have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. It is not necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

*In re Keller*, 642 F.2d 413, 288 USPQ 871 (1981). The '933 patent teaches that a peptide that consists of 50% of SEQ ID NO: 12 mimics the FG ridge of the D4 domain of CD4 and thus

are important in the formation of intramolecular bonds associated with immunological activity in column 8. Thus the '933 patent teaches a peptide of therapeutic interest in the treatment of immune disease. Harlow et al. teaches that antibodies are useful for purification and quantification of peptides. Thus it would be obvious to the artisan of ordinary skill to generate antibodies against the peptide, which would also be antibodies against instant SEQ ID NO: 12, because one of ordinary skill would readily appreciate the usefulness of such antibodies in purifying, quantifying, and otherwise investigating the characteristics of the '933 peptide. The state of the antibody art, as indicated by the publication of Harlow et al., is sophisticated, predictable, and well developed, and the artisan of ordinary skill in the biomedical arts would readily appreciate the usefulness of generating antibodies to peptides of therapeutic interest.

In reference to Applicant's argument that impermissible hindsight was used in the search, it is agreed that knowledge of Applicant's invention is required to search for the full scope of the prior art that might anticipate or render obvious that invention. Such a search is not impermissible hindsight but is rather required of the Examiner. See MPEP §904.

CLAIMS 21 AND 32 ARE REJECTED. CLAIMS 29-31, 33, AND 34 ARE ALLOWED.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.  
20 July 2004



JANET ANDRES  
PRIMARY EXAMINER